

### REMARKS

Claims 71 and 72 have been added. Support for the new claims can be found throughout the specification, for example, at pages 13-14.

Claims 10, 13, 44-47, 56-67, 69 and 70-72 are pending.

### CLAIM REJECTIONS

Claims 56-66, 69 and 70 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,176,927 (“Haarasilta”) or Poutanen (1997, of record) (“Poutanen”) in view of Paice, et al. (1996, of record) (“Paice”) or Wolf, et al. (1995, of record) (“Wolf”) and U.S. Patent No. 5,405,769 (“Campbell”).

Claim 67 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Haarasilta or Poutanen in view of Paice or Wolf and Campbell and further in view of Autio, et al. (1996, of record) (“Autio”).

Claims 57-59 depend from independent claim 56, and claims 61-67 and 69-70 depend from independent claim 60.

Claim 56 recites a bakery product or a dough for making a bakery product including a polypeptide expressed from the nucleotide sequence of SEQ ID NO: 6, where said bakery product or dough for making a bakery product is suitable for use in a foodstuff.

Claim 60 recites a dough for making a bakery product prepared by incorporating a bacterial xylanase including a polypeptide expressed from the nucleotide sequence of SEQ ID NO: 6, where the resultant dough is less sticky than an otherwise identical dough prepared by incorporating a fungal xylanase instead of said bacterial xylanase.

#### ***Campbell Does Not Provide Motivation to Combine the Cited References***

The Board of Patent Appeals and Interferences (“the Board”) has found that Campbell discloses that a polypeptide expressed from a nucleotide of SEQ ID NO: 6 has xylanase activity. See Decision, page 6, FF 3. The Board has stated that “Campbell discloses that a xylanase which undisputedly meets the requirements of claim 56 has thermostable properties which makes the xylanase beneficial ‘for example, [in] **food processing at elevated temperatures**’ (Campbell, col.1, ll. 66-67 (FF 5)).” See Decision, pages 12-13.

The Board uses the assertion that the wild-type xylanase of Campbell is thermostable as the motivation to select the xylanase expressed from the nucleotide of SEQ ID NO: 6 or having the amino

acid sequence of amino acids 29-213 of SEQ ID NO: 5 from the hundreds of available xylanase enzymes for use in a method of involving baking, as shown below:

"Further, xylanases were well known in the art to impart desirable properties to doughs and bakery products (FF 4, 6-11). Thus, in view of the prior art cited by the Examiner, an ordinary artisan would have been advised that a polypeptide expressed from SEQ ID NO: 6 not only possessed the xylanase activity known to be advantageous in bakery products, **but was thermostable and therefore beneficial in methods involving food processing at elevated temperatures.** Given these teachings, we agree with the Examiner that the ordinary artisan would have been prompted to include a polypeptide expressed by SEQ ID NO: 6 in a bakery product or dough, as required by claim 56.

We note, as Appellants urge, that certain xylanases, bacterial xylanases among them, were known to produce sticky dough (FF 11, 12). However, given the numerous teachings of the advantageousness of adding xylanases to bakery doughs (FF 4, 6-11), we are not persuaded that an ordinary artisan would have been dissuaded from including a xylanase expressed from SEQ ID NO: 6 in bakery products, **particularly in view of that xylanase's beneficial thermostability** (FF 5).

Rather, it would have equally reasonable for an ordinary artisan to arrive at a conclusion opposite than that advanced by Appellants; that is, one could conclude that Campbell, having cited Maat, was aware of the stickiness issues with certain xylanases, **yet felt that the thermostability of the enzyme expressed from SEQ ID NO: 6 nonetheless outweighed such concerns when using the enzyme to aid in food processing at elevated temperatures**, such as occurs, for example, in baking (FF 5)."

See Decision, pages 13-14, emphasis added.

It may be true, as Appellants urge (App. Br. 12), that the claimed xylanase is but one of several hundred possible xylanases that might have been added to dough. **However, Campbell explicitly states that the claimed xylanase is thermostable (FF 3), a property that makes it beneficial in methods of processing foods at elevated temperatures (FF 5), which is of course exactly what baking involves.** Thus, given the prior art cited by the Examiner, we are not persuaded that selecting the claimed xylanase for use in a bakery dough would have amounted to an ordinary artisan attempting to find the proverbial needle in a haystack.

See Decision, page 14, emphasis added.

As pointed out by the Board, Campbell "explicitly states that the claimed xylanase is **thermostable.**" See Decision, page 6, FF 3 citing Campbell, Abstract; and Decision, page 14. Further, Campbell states that "[s]everal of these application [sic] could benefit from a thermostable xylanase, for example **food processing at elevated temperatures.**" See Campbell, col. 1, lines 65-68.

Finally, as stated by the Board, processing foods at elevated temperatures "**is of course exactly what baking involves.**" See Decision, page 14. Consequently, Campbell provides motivation for selecting the *B. circulans* xylanase for use in food processing at elevated temperatures, e.g. baking.

Significantly, while the xylanase effects on the dough may, in turn, have an effect on the baked product (See Specification, Example 3), the xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 is **not used in baking**, but rather is used in the development of dough prior to baking. This fact is supported by the Declaration of Jens Frisbaek Sorensen at paragraph 3 (Sorensen Declaration, attached). The use of the xylanase in the creation and development of dough is emphasized in the Specification, which states that the present invention seeks to provide a solution to the problem of **providing a dough** which is non-sticky and does not have adverse handling problems. See Specification, page 3, lines 16-21. Additionally, Experiment 1 was performed to compare the results obtained with the bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 to other xylanases. See Specification, Experiment 1. In Experiment 1, the doughs including the various xylanases were **never baked or subjected to high temperatures.** *Id.* Instead, the doughs were "rested" for 10 or 45 minutes. *Id.*

As the xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 or having the amino acid sequence of amino acids 29-213 of SEQ ID NO: 5 is used in the development of dough for making a bakery product, the xylanase is **not used in food processing at elevated temperatures.** As stated in the Sorensen Declaration, dough for making a bakery product is typically developed at a temperature within the **range of 20-40°C.** See Sorensen Declaration, paragraph 3.

Because the claimed invention uses the xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 or having the amino acid sequence of amino acids 29-213 of SEQ ID NO: 5 during the development of dough at lower temperatures, the teaching of Campbell that the *B. circulans* xylanase would be beneficial for food processing at elevated temperatures does not provide the motivation for selecting the xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 from the hundreds of available xylanases. Consequently, Campbell does not provide motivation to combine the teachings of Paice, Wolf or Campbell with the teachings of Haarasilta or Poutanen.

**The Claimed Invention Is Patentable Over the Cited Reference Because the Claimed Invention Demonstrates Unexpected Results**

In the Decision, the Board stated, “Nor are we persuaded that Appellants have advanced **sufficient evidence** of unexpected results to outweigh the evidence of unexpected results to outweigh the evidence of *prima facie* obviousness.” See Decision, page 14. The Board continued:

As noted above, “[m]ere improvement in properties does not always suffice to show unexpected results ....[W]hen an applicants demonstrates *substantially* improved results...and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence* of evidence to the contrary.”

See Decision, page 15, original emphasis, citing *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995). Finally, the Board stated, “Appellants **point to no assertion in the Specification** that this was a surprising or unexpected result, or a substantial improvement.” See Decision, page 15.

A declaration, when timely presented, containing evidence of unexpected results must be considered by the Examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. §103. See MPEP § 716.01(a). A declaration submitted under 37 CFR 1.132 can be considered timely filed when submitted after an appeal if the declaration is filed with a request for continued examination. See MPEP § 716.01. Applicants submit the Declaration of Jens Frisbaek Sorensen, filed herewith, as evidence that the claimed invention demonstrates unexpected results, which are indicia of nonobviousness. See MPEP § 716.01(a).

Applicants have demonstrated the unexpected result that a xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 having the amino acid sequence of amino acids 29-213 of SEQ ID NO: 5 produces a significantly less sticky dough as compared with other xylanases, including other bacterial xylanases. See Specification, Example 1. In Example 1 of the Specification, the bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO: 6 having the amino acid sequence of amino acids 29-213 of SEQ ID NO: 5 (“BX xylanase”) was compared with another bacterial xylanase (“Röhm xylanase”), which differs from the BX xylanase by only a few amino acids. See Specification, pages 48-49. At the time of invention, it was known in the field that bacterial xylanases produced very sticky dough. See Sorensen Declaration, paragraph 4; Specification, page 2, lines 16-17. As predicted, Röhm gave rise to dough stickiness. See Sorensen Declaration, paragraph 5. Surprisingly, the BX xylanase produced dough that was less sticky than the control dough. See Specification, Table 4. As stated in the Sorensen Declaration, this was unexpected because it was anticipated that a bacterial xylanase would produce sticky dough. See Sorensen Declaration, paragraph 5.

Unpredictably, the BX xylanase not only produced dough that was less sticky than a control dough, the BX xylanase produced dough that was less sticky than a dough containing a fungal xylanase. See Sorensen Declaration, paragraph 6. In Example 1 of the Specification, two fungal xylanases (“X1 xylanase” and “Novo xylanase”) were compared with the BX xylanase. See Specification, page 47, line 13 – page 48, line 13. As shown in Table 2, the BX xylanase, decreased the stickiness of the dough compared to the control, while the X1 and Nova xylanases gave rise to dough stickiness. See Specification, page 47, lines 10-14 and Table 2. The BX result was unexpected because, as stated above, it was anticipated that a bacterial xylanase would produce sticky dough. See Sorensen Declaration, paragraph 6. However, it was even more surprising that the BX enzyme could reduce the stickiness of the dough when compared to a fungal xylanase, because fungal xylanases are known to increase the specific volume of breads without giving rise to dough stickiness. See Sorensen Declaration, paragraph 6; Specification, page 2, line 30-33.

“[W]hen an applicant demonstrates substantially improved results...and **states that the results were unexpected**, this should suffice to establish unexpected results *in the absence* of evidence to the contrary.” See Decision, page 15, original emphasis, citing *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995). As evidenced by the Sorensen Declaration, the results obtained from the claimed invention were unexpected. Additionally, the Examiner has not offered any evidence to contradict that bacterial xylanases were known to produce sticky dough.

Instead, the Examiner pointed to Maat and suggested that it is not the source of the xylanase, but rather the purity of the xylanase, which causes the differential effects of xylanases on the stickiness of dough. See Examiner’s Answer, page 16. The Examiner has also suggested that the results of Example 1 may be due to differences in the purity of the xylanases. *Id.* Applicants respectfully traverse this contention.

Maat does not teach that the purity of the xylanase affects the stickiness of dough. Instead, Maat states, “**Not only the type** but also [the enzyme] **quantities** vary from one preparation to another, which hampers the application of these preparations in the bakery.” See Maat, page 353. Therefore, Maat actually teaches that **the quantity, and not the purity**, of the enzyme can affect the application of the enzyme to preparations in the bakery. This is significant because the quantity of enzyme, as measured by the enzyme activity of each sample, is reported in Example 1 of the Specification. See Specification, pages 46-49. Therefore, the Examiner’s argument regarding the purity of the xylanases being predictive of dough stickiness is unsupported. Nonetheless, the xylanases used in Example 1 of the Specification were greater than 90% pure as demonstrated by

Applicant : SIBBESEN, et al.

Attorney's Docket No.: 14923.0104

Serial No. : 10/626,583

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Page : 10 of 10

HPLC chromatograms, which further counters the Examiner's assertion. See Sorensen Declaration, paragraph 7.

In sum, Applicants have established that the results yielded by the claimed invention are unexpected in view of the prior art. Accordingly, it is respectfully submitted that the rejection is overcome and respectfully requested that the rejection be withdrawn.

### **PATENTABILITY OF NEW CLAIMS**

Claims 71 and 72 have been added. Claim 72 depends from independent claim 71.

Claim 71 relates to a method for reducing the stickiness of a dough for making a bakery product comprising incorporating a polypeptide expressed from the nucleotide sequence of SEQ ID NO: 6 in the dough, wherein said dough for making a bakery product is suitable for use in a foodstuff.

As discussed above, the cited references do not provide the motivation for selecting a polypeptide expressed from the nucleotide sequence of SEQ ID NO: 6 for use in a dough, specifically, for reducing the stickiness of dough. Also discussed above, the use of a polypeptide expressed from the nucleotide sequence of SEQ ID NO: 6 showed the unexpected result of reducing the stickiness of dough, which is particularly relevant to the new claims. Therefore, for at least the reasons discussed above, claims 71 and 72 are patentable over the references of record.

### **CONCLUSION**

Applicant believes that the claims are in condition for allowance. Should any fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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